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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,408	01/23/2002	Takashi Sera	109845-139	3337
28089	7590	02/25/2004		
HALE AND DORR LLP 300 PARK AVENUE NEW YORK, NY 10022			EXAMINER WESSENDORF, TERESA D	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,408

Applicant(s)

SERA, TAKASHI

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) 4-8 and 11-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-10; the species-a subset of the library and transcriptional activator is acknowledged.

Claims 4-9 and 11-86 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse.

Status of Claims

Claims 1-86 are pending.

Claims 4-8 and 11-86 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species.

Claims 1-3 and 9-10 are under examination.

Specification

The disclosure is objected to because of the following informalities: Example 3 is unclear in the recitation that only Seq. ID. No. 27 shows significant binding and at the same breath recites that Seq. ID. Nos. 27, 28 or 29 has very little binding.

Appropriate explanation and/or correction are required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors {e.g., grammatical (see col.5, paragraph [0083]), typographical and idiomatic}. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The specification fails to provide an adequate description for the claimed method in which each of the zinc fingers contained in the ATP is rationally designed. The specification describes the rational designing of the specific Zinc fingers SpIC or Zif268 and SpI using specific code at positions -1, 2, 3, and 6 of the alpha helical region of the ZFP from four-base pair nucleotide target sequences. See e.g., Tables 1-3. However, it cannot be ascertained from the rational design of the specific ZFP using the specific code, the other ZFP that can be rationally designed by other codes, singly or in multiple combinations. The disclosure is replete with general teachings as to the claimed method. The exemplification is described in specific terms. Even with the specific descriptions given in the examples, one cannot predict the applicability to the numerous zinc fingers and different codes. Example 3 of the instant specification demonstrates how this is not possible. In the determination of DNA Base Specificity, with the aspartic acid at position 2 in the first zinc finger domain it is expected that binding will occur to the cytosine at the 3' end of the 4 base pair region (See Fig. 3). However, significant binding of the AL1 ZFP only

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occurred when the protein was incubated with SEQ ID NO: 27. Very little binding to SEQ ID NOS: 27, 28, or 29 was observed, thus confirming the specific interaction of aspartic acid at position 2 with guanine at the 3' end of the four base pair region, not with any bp. If this specific description does not produce the desired result, how much more for a general claim to any ZFP using any codes. There is no guidance or little direction provided to a skilled in the artisan to extrapolate the single specific description to all or any type of ZFP using any code system. There is no teaching in the specification as to the conditions necessary for rationally designing any type of ZFP with any kind of code, singly or in multiples, other than those specifically described therein. See *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003).

The specification further fails to provide a description of screening a subset of members of said library. None of the detailed description describes screening of a subset of members of a library. Neither was a definition provided as to kind, number and/or length that make up a subset of a library.

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Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 1 is indefinite as to the context by which the target site is "associated" with the gene. The term "more" or "subset" is a relative term, which renders the claim indefinite. The term "more" or "subset of a library" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Step (b) is unclear as to the alternative step of "screening" or "selecting". The selecting step usually follows a screening step and not either one or the other. Step (d) is unclear as to the measure of a "smaller subset" relative thereto. "The desired gene" lacks antecedent basis from the preceding steps or preamble.

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B). Claim 2 is confusing as to the alternative used of transcriptional activator or "protein domain" that exhibits transcriptional activation activity. The difference(s) between these two is unclear within the claimed context.

C). Non-sequitur for "said first screening or selecting step" in claim 10.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Choo et al [U.S.6,007,988 (I) or U.S. 6,492,117 (II)]. (The rejection is based on individual members and not a subset of a library being screened).

Choo et al (I) discloses at col. 3, line 45 up to col. 4, line 59 a method in of selecting zinc fingers of Zif 268 (ATF, as claimed) with DNA-binding specificities comprising constructing a library in which the first finger of Zif268 is randomised, and screening with tetranucleotides to take into

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account end effects such as additional contacts from variants of this finger. Only 4 positions (-1, +2, +3 and +6) were randomized (rationally designed as claimed). See col. 17, line 63 up to col. 18, line 5. The claimed artificial transcription factor is inherent to the prior art teachings of the components i.e., zinc finger contained in the ATF. Likewise, the 256 four-base pair is inherent to the prior art target for the ZFP code since a 3 or 4-bp target is usually present in ATF binding target. (Note the instant Examples which does not positively recite said 256 numbers but appear to disclose said inherent number present in a target). See further col. 7, line 64 up to col. 8, line 16; col.11, Example 1 up to col. Choo et al (II) basically discloses the same method as Choo (I) and further discloses the step of identifying of the molecule that binds to a G-quartet nucleic acids. See the Examples.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-3 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choo (either I or II) in view of Rebar et al (Science).

Choo (I or II) is discussed, supra. Choo does not recite the screening of library members by subset. However, Rebar discloses at page 671, col. 2 and Table 1, page 672 screening by phage with a GACC and GCAC pools i.e., a subset of a library, as claimed. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to screen the library of Choo (I or II) by subset in the manner as taught by Rebar. Screening by subset is conventionally done in phage screening or selection. One having ordinary skill in the art would have been motivated to screen by subset for an efficient screening of groups with the library members being better represented.

No claim is allowed.

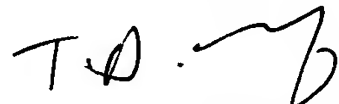
Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be

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reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

February 21, 2004